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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,557	06/20/2003	Sebastian Vogt	100727-55/Heraeus 407-KGB	6050
27384	7590	07/03/2006	EXAMINER	
NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD AVENUE 18TH FLOOR NEW YORK, NY 10022			SILVERMAN, ERIC E	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/600,557	Applicant(s) VOGT ET AL.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input checked="" type="checkbox"/> Other: <u>NPL</u> |

DETAILED ACTION

Receipt of applicants' response, amendment, and arguments, filed 5/16/2006, is acknowledged. Claim 9 was added. Claims 1 – 9 are pending in this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1 – 8 under the second paragraph of 35 U.S.C. 112 is **withdrawn** in light of amendment.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites a "method of treating an antibacterial infection". It is unclear what is meant by an antibacterial infection. For the purposes of compact prosecution, this claim will be interpreted to mean a method of treating a bacterial infection. Clarification is requested.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4, 5 and 7 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,797,873 to Franz et al for reasons of record and those discussed below.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. In response to applicants' argument that the teicolanin is not disclosed to be powdery, it is noted that in the method of making the compositions of Franz, the drug is dissolved in a solvent (see example). The artisan would recognize that powdered solids dissolve more easily than compressed solids, and thus, would find it obvious to use a powdered form. This teaching is deemed to be implicit in the teaching of dissolving the dosage form of Franz. Further, upon evaporation of the solvent, it is understood that the drug will become a powdery solid, dispersed with the other ingredients formerly dissolved therewith. Again, this teaching is understood to be implicit in Franz.

With regard to the argument that the Franz does not teach use of drugs in a water soluble salt form, Franz is suggestive of using the methotrexate, the drug of the examples, as a sodium salt (col. 4, lines 37 – 38). Sodium salts are understood to be water soluble. This is further supported by the fact that the solubility of the salt in organic solvents is recited to be low, for example, as little as 0.1% by weight (col. 4, lines 67 – 45). Although this teaching is directed at only the drug used for the examples, and not the drugs of instant claims, the artisan would understand that when using the drugs of instant claims (which are also preferred ingredients in the invention, see paragraph bridging col.'s 3 and 4), the suggestion to use the sodium salt would still hold. As such, Franz does teach the use of water soluble salts of the drugs.

With regard to the argument that Franz does not specifically teach combining these agents, it is generally considered to be prime facie obvious to combine

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compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional drugs used in bone cements in a bone-cement composition. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

With regard to the argument that Franz does not teach the use of teicolanin as a first drug and one of the other recited drugs as a second drug, it is noted that the designation of "first" and "second" is artificial, and is only used for convenience to refer to one drug or another specifically. For reasons discussed in the previous office action and *supra*, the combination of drugs, which defines the invention of instant claims, is rendered obvious by Franz.

Claim 3 **remains** rejected 35 U.S.C. 103(a) as being unpatentable over US 5,797,873 to Franz et al in view of US 4,588,583 to Pietsch for reasons of record and those discussed below.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant avers that Pietsch does not remedy the alleged deficiencies in Franz. These supposed deficiencies have been discussed, *supra*.

Claim 6 **remains** rejected 35 U.S.C. 103(a) as being unpatentable over US 5,797,873 to Franz et al in view of US 4,283,799 to Pratt et al for reasons of record and those discussed below.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive. Applicant avers that Pratt does not remedy the alleged deficiencies in Franz. These supposed deficiencies have been discussed, *supra*.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,797,873 to Franz et al in view of Salaria in Indian Pediatrics, 2001, 38: 372-375.

The teachings of Franz have been discussed. Franz does not teach a method of treating a bacterial infection.

Salaria teaches that teicoplanin is known in the art as an antibiotic.

Thus, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use the composition of Franz, which includes teicoplanin, to treat a bacterial infection. The motivation comes from Salaria, who teaches that teicoplanin is well known to treat at least some types of bacteria. It is generally obvious to use a material for its art-intended purpose, and the artisan would enjoy a reasonable expectation of success in doing so.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 1615



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